SEP 1 2 2001

510(k) SUMMARY K012871

SUBMITTED BY

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August 24, 2001

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR §807.92.

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME
Classification Name: Spinal Intervertebral Body Fixation Orthosis
Common/Usual Name: Anterior and Posterior Spinal Implants
Product Classification: Class II
Proprietary Name: Synergy™ Ti Fenestrated Integral™ Open Screws

PREDICATE DEVICE
The predicate device is the INTERPORE CROSS International Synergy Integral Open Screw for anterior and posterior use, which was previously cleared under 510(k)'s K934429 and K940631.

INDICATIONS-FOR-USE
The Synergy Spinal System implants are intended to be used as a temporary construct that assists normal healing and are not intended to replace normal body structures. They are intended to stabilize the spinal operative site during fusion procedures and should be removed after fusion.

The implants are attached to the spine posteriorly by means of hooks and/or screws joined with rods and anteriorly by means of vertebral screws joined with rods.

As a pedicle screw system, the Synergy Spinal System is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are having the screws fixed or attached to the lumbar and sacral spine; (c) who are receiving fusions using autogenous bone graft only; and (d) who are having the device removed after the development of a solid fusion mass. The levels of screw fixation are L3 to S1/Ilium.

In addition, the pedicle screw system may also be used to provide immobilization and stabilization of spinal segments, in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

As a posterior, non-pedicle, screw and hook system, and an anterolateral, intervertebral body screw system, the specific indications for the Synergy Spinal System are:

1. Degenerative Disc Disease (as defined by chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
2. Idiopathic scoliosis.
3. Kyphotic deformities of the spine.
4. Paralytic scoliosis and/or pelvic obliquity.
5. Lordotic deformities of the spine.
6. Neuromuscular scoliosis associated with pelvic obliquity.
7. Vertebral fracture or dislocation.
8. Tumors.
9. Spondylolisthesis.
10. Stenosis.
11. Pseudarthrosis.
12. Unsuccessful previous attempts at spinal fusion.

For posterior, non-pedicle, screw use, the Synergy screws and lateral connectors are intended for sacral/iliac attachment only, and the Synergy hooks and transverse connectors are intended for posterior thoracic and/or lumbar use only. As a whole, the levels of use are T1 to the Sacrum/Ilium.

The Adjustable Length Rod is intended for in situ adjustment after placement of the hooks or screws during spinal fusion surgery.

For anterior use, the recommended levels of attachment are: T10 – L3 for the double rod constructs and T5 – L5 for the single rod construct. The 4.75 mm diameter rod system can be used in single and double rod constructs while the 6.35mm diameter rod system is to only be used in single rod constructs. In all cases, instrumentation must be at least 1 cm from any major vessel.

DEVICE DESCRIPTION

The Synergy™ Spinal System components are grouped as follows:

Posterior Application:

1. Integral™ Open, Closed, Angled Closed and Reduction Screws, Variable Locking Screws with Variable Locking Seats, and Iliac Screws with Nuts and Set Screws. Only the Integral™ Open, Closed, Reduction and Variable Locking Screws are intended for pedicle fixation.

2. Open and Closed Spinal Hooks with Sliders, C-rings and Set Screws.
3. Adjustable and Fixed Transverse Connectors with Set Screws.
4. Closed and Axial Rod Connectors with Set Screws.
5. Lateral Connectors with Set Screws.
6. Rods and Adjustable Length Rods and Set Screws.
7. Instruments.
8. Sterilizer case(s).

Anterior Application:

1. Integral™ Open and Closed Screws and Variable Locking Screws with Variable Locking Seats, with Nuts and Set Screws.
2. Vertebral Washers.
3. Fixed Transverse Connectors with Set Screws.
4. Rods.
5. Instruments.
6. Sterilizer case(s).

NOTE: While the Variable Locking Screws and some fasteners (nuts and set screws) are used for both the 6.35mm and 4.75mm rod sizes, the remaining components (except for those connector components that are designed to join the two rod sizes) are designed for specific rod diameters.

NOTE: The Adjustable Length Rod is intended for in situ adjustment after placement of the hooks or screws during spinal fusion surgery.

The Adjustable Length Rod is intended for use as part of either a single or double rod assembly. The Adjustable Length Rod allows for distraction at a central location once the bone anchors have been secured.

COMPARISON TO THE PREDICATE DEVICE

The Synergy Ti Fenestrated Integral Open Screw spinal implants are technologically substantially equivalent to the previously cleared Synergy Integral Open Screws. Both implants are used to treat the same conditions, have the same precautions and contraindications for use, and have equivalent potential for complications associated with the risk of use. In addition, they both represent a long standing, basic design concept and in terms of safety and effectiveness, differ only in minor details. Based on the basic design concept, the use of established well-known materials, feature comparisons, mechanical testing, indications for use, surgical approach, preproduction quality assurance planning and engineering analysis, INTERPORE CROSS International believes that sufficient evidence exists to reasonably conclude that the Synergy Ti Fenestrated Integral Open Screws are substantially equivalent to existing legally marketed spinal implants.

DISCUSSION OF NONCLINICAL TESTS

Data regarding the functional performance of the Synergy Ti Fenestrated Integral Open Screws has been generated. Mechanical testing indicates that the Synergy Ti Fenestrated

Integral Open Screws meet or exceed all functional requirements and support their suitability for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 2 2001

Ms. Lynn Rodarti
Manager, Regulatory and Clinical Affairs
Interpore Cross
181 Technology Drive
Irvine, California 92618-2402

Re: K012871
Synergy™ Spinal System – Synergy Ti Fenestrated Integral Open Screws
Regulation Numbers: 888.3050, 888.3060, and 888.3070
Regulation Names: Spinal Interlaminal Fixation Orthosis; Spinal Intervertebral Body Fixation Orthosis; Spondylolisthesis Spinal Fixation Device System; and Pedicle Screw Spinal System
Regulatory Class: II
Product Codes: KWP; KWQ; MNI; and MNH
Dated: August 24, 2001
Received: August 27, 2001

Dear Ms. Rodarti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K012871

Device Name: **Synergy Ti Fenestrated Integral Open Screws**

Indications-For-Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

Prescription Use _____ Over-The-Counter Use
(PER 21 CFR 801.109)

510(k) Number K012871
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(Optional Format 1-2-96)

510(k) Number (if known):

Device Name: Synergy Ti Fenestrated Integral Open Screws

Indications-For-Use (cont'd):

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(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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